

# Risk Associated with Electrocardiogram (ECG)

Risk Classification Under Medical Device Rules, 2017 Class C  
(Moderate to High Risk)

## Potential Risks

- Interference from Other Electronic Devices
- Calibration and Maintenance Issues
- Lead Reversal Errors
- Signal noise or artifacts
- Inconclusive Results Leading to Additional Testing
- Slight Risk of Electrical Shock
- Skin Irritation & allergy

## Precautions to be Taken

- Proper Electrode Placement
- Check for Loose or Defective Electrodes
- Minimize Movement
- Control Environmental Interference
- Ensure Proper Machine Calibration

Any adverse event associated with these devices can be reported via following tools:-



**HELPLINE**  
**1800 180 3024**

Available from: Monday to Friday  
(9:00 AM to 5:30 PM)



**MDAE**  
**Reporting Form**

Available on: [www.ipc.gov.in](http://www.ipc.gov.in)



**MDAE**  
**Monitoring Centre**

List Available on: [www.ipc.gov.in](http://www.ipc.gov.in)



**Adverse Drug**  
**Reactions**  
**Monitoring System**

<https://adrmsipc.in/adrms/index.html>

Issued in Public Interest:

**INDIAN PHARMACOPOEIA COMMISSION**

National Coordination Centre, Materiovigilance Programme of India, Ministry of Health & Family Welfare, Govt. of India  
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